

Notice of Allowability

Application No.

09/977,874

Examiner

Louise N. Leary

Applicant(s)

MARSHALL ET AL.

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Request for Continued Examination filed 1-21-2004.
2. ☒ The allowed claim(s) is/are 1-3 and 7-33.
3. ☒ The drawings filed on 15 October 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

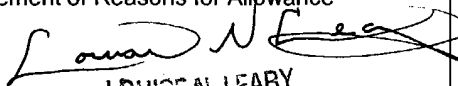
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


LOUISE N. LEARY
PRIMARY EXAMINER

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the claims:

In claim 31, line 2, add a ---.--- after "silica".

2. The following is an examiner's statement of reasons for allowance:

The reasons for allowance of the claims is that none of the prior art of record disclose or suggest (I) a material for detecting the presence of urease in a gastric material for diagnosing a gastrointestinal disorder comprising a composition that comprises a powder including urea and an indicator that is configured to indicate the presence of ammonia created when the urea contacts urease, said urea having a mean particle size of less than about 0.1mm; (II) a material for detecting the presence of urease in a gastric material for diagnosing a gastrointestinal disorder comprising a composition that comprises a powder including urea and an anti-caking agent, said urea being converted to ammonia when contacted with urease, said composition further comprises a dry indicator being configured to indicate the presence of ammonia thereby indicating the presence of urease; (III) a composition for detecting the presence of urease in a gastric material for diagnosing a gastrointestinal disorder comprising urea and an anti-caking agent, said urea being in the form of a powder having a mean

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particle size of less than about 0.05mm, said anti-caking agent comprising a material selected from the group consisting of silica and sodium aluminosilicate, said anti-caking agent having a mean particle size of less than about 0.05mm; (IV) a material for detecting the presence of urea in a gastric material for diagnosing a gastrointestinal disorder comprising a composition comprising a powder, the composition including urea and a bactericide, the urea having a mean particle size of less than about 0.1mm; (V) a product for detecting the presence of urease in a gastric material for diagnosing a gastrointestinal disorder comprising a container defining a well, a composition contained within the well that includes urea and an anti-caking agent, the composition being a finely powdered state, the urea and the anti-caking agent having a mean particle size of less than about 0.1 mm as claimed in the present invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 10 to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571)272-0961. The fax phone

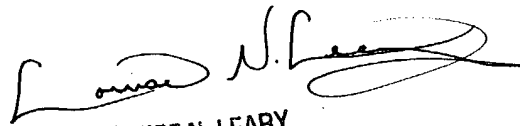
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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY
PRIMARY EXAMINER

February 5, 2004